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THIS ISSUE

Bone Growth Stimulators and Tobacco Use Cessation for Spinal Fusions

TO:

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CONTACT:

Jami Lifka
Office of the Medical Director
PO Box 44321
Olympia WA 98504-4321
360-902-4941

Provider Toll Free
1-800-848-0811
902-6500 in Olympia

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Purpose

This Provider Bulletin communicates two amended policies. The first policy, claims administration policy 40.03, describes under what circumstances the insurer will pay for the different types of bone growth stimulators. It replaces interim policy 40.03.

The second policy, claims administration policy 40.17, describes when the insurer will pay for smoking cessation products. This policy statement replaces the smoking deterrent portion of PB 93-30.

Both policies pertain to the State Fund and Self-Insured employers. Both policies have an effective date of November 1, 2003.

Bone Growth Stimulators

Several types of bone growth stimulators are reported to aid in the healing of bone fractures.

- **Non-invasive or external stimulators:**

  This category of stimulators is further differentiated into those that create a small electrical current and magnetic field or those that provide a low-intensity pulsed ultrasonic wave to the fracture site.

- **Implantable or invasive stimulators:**

  This type of stimulator applies an electrical current directly to the bone.

When will the insurer pay for the use of a bone growth stimulator?

The insurer will pay for a bone growth stimulator when it is proper and necessary, when the adjudicator has provided prior authorization, and when the indications for use match the approved indications under policy 40.03.

What are the approved indications under policy 40.03?

1. **The non-invasive ELECTRICAL bone growth stimulator is covered only for the following indications:**

    a) The stimulator will be used for a nonunion of long bones, and the fracture site shows no visibly progressive signs of healing.

    - Long bones include the clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal and metatarsal bones.

    - Nonunion of a fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone growth stimulator, separated by at least 90 days, each including multiple views of the fracture site. The baseline radiograph is the one done at the time of injury or, if surgery took place, then from the date of surgery. A written interpretation by a physician must be included stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

    OR

    b) The stimulator will be used for spinal applications for a failed fusion where a minimum of 9 months has elapsed since the last surgery.

2. **The non-invasive ULTRASOUND bone growth stimulator is covered only for the following indications:**

    a) The stimulator will be used on a nonunion of bone. Nonunions of the skull, vertebrae, and those that are tumor-related are excluded from coverage.

    Note: Coverage for ultrasound stimulators includes nonunion of bones that are not long bones. For example, ultrasound stimulation for a nonunion of the scaphoid bone in the wrist may be covered.

    AND

    b) Nonunion of a fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone growth stimulator, separated by at least 90 days, each including multiple views of the fracture site. The baseline radiograph is the one done at the time of injury or, if surgery took place, then from the date of surgery. A written interpretation by a physician must be included stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

    AND

    c) The patient must have failed at least one surgical intervention for the treatment of the fracture.

3. The IMPLANTABLE bone growth stimulator is covered only for the following indications:

a) Nonunion of long bone fractures,

- Nonunion of a fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the bone growth stimulator, separated by at least 90 days, each including multiple views of the fracture site. The baseline radiograph is the one done at the time of injury or, if surgery took place, then from the date of surgery. A written interpretation by a physician must be included stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

OR

b) As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion.

NOTE: For State Fund claims, a utilization review vendor will make a recommendation to the department as to whether an implantable stimulator is medically appropriate. The department determines whether the treatment is proper and necessary.

What are the billing codes that are associated with bone growth stimulators?

Billing Code	Device	Prior-Authorization
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal application	Required
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal application	Required
E0749	Osteogenesis stimulator, electrical (surgically implanted)	Required
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive	Required

Payment for Smoking Cessation Products for Spinal Fusion Candidates

Under most circumstances the insurer will not pay for smoking cessation products, hereafter referred to as tobacco use cessation products.

Exception: The insurer may pay for tobacco use cessation products when the worker is considered a strong candidate to undergo a spinal fusion and the physician has instructed the worker to cease using all tobacco products (smoking or chewing tobacco) for a period of time necessary for the spinal fusion to be effective. This is because the rate of fusion failure is at least doubled in smokers as compared to non-smokers.

Under what circumstances are tobacco use cessation products covered?

1. **The insurer may pay for tobacco use cessation products for a worker who will undergo spinal fusion when specific criteria are met.**
   Smoking or any tobacco use does not meet the definition of an industrial injury or occupational disease and the insurer will not accept it as a condition under a claim. However, pursuant to WAC 296-20-055, the insurer may authorize temporary treatment with smoking cessation products when all of the following criteria are met:
   - The physician recommends a spinal fusion and the worker meets department guidelines for the fusion;
   - The worker currently uses one or more tobacco products daily;
   - The attending physician has instructed the worker to cease using tobacco products for a period of time necessary for the spinal fusion to be effective;
   - The attending physician has concluded that smoking cessation products are necessary for the worker to stop using tobacco products, and
   - The worker has not failed a course of smoking cessation which was paid for by the department or self-insured employer on this claim.

2. **Prior authorization is required for the insurer to pay for tobacco use cessation products for a spinal fusion.**

3. **For State Fund claims: All parties must sign the authorization letter.**
   The attending doctor and the worker must sign and return the authorization letter that will be sent from the State Fund claim manager. This letter will serve as a memorandum of understanding between the department, the worker and the attending doctor.

4. **The worker will obtain the tobacco use cessation product from the pharmacy.**
   The worker should obtain Zyban (bupropion HCl) and over-the-counter nicotine replacement therapy products through the pharmacy with a prescription from the physician. The pharmacy can then bill the insurer directly.

5. **Timing of nicotine withdrawal relative to the spinal fusion is important.**
   - If the surgeon will not do surgery while the worker is using tobacco products, the worker must stop using tobacco products and nicotine containing cessation products for 90 days prior to the surgical procedure for the spinal fusion to be approved.
   - There is an expectation that the worker remains nicotine free for 180 days post spinal fusion.
   - Upon request of the physician, the department may require as a condition of authorizing the spinal fusion that the injured worker demonstrate through a urine test that no nicotine metabolites are present.

6. **The worker must use department-approved tobacco use cessation products.**
   In order for the insurer to pay for the tobacco use cessation products, the worker must use a smoking cessation product on the department-approved list. Approved products include Zyban (bupropion HCl), nicotine patches, nicotine gum, and nicotine lozenges. A person may use a combination of Zyban (bupropion HCl) and nicotine replacement therapy.

   It is common practice to use a nicotine inhaler or spray for more than 3 months. However, this length of time is not acceptable in the preparation of spinal fusion surgery. Therefore, the insurer will not purchase nicotine inhalers or sprays.

7. **Payment for tobacco use cessation products is authorized on a temporary basis.**
   The insurer will limit payment to the following:
   - Up to 12 months use of Zyban/bupropion HCl (6 months before surgery, 6 months after surgery), and/or
   - 3 months use of nicotine patches, gum or lozenges, 3 months prior to surgery.
   - Continuation of payment authorization up to these limits is at the discretion of the insurer. For example, authorization may be discontinued if there is evidence that the worker is smoking 2 months after beginning use of smoking cessation products.

8. **Authorization to pay for tobacco use cessation products is done on a one time only basis per claim.**
   The insurer may pay for tobacco use cessation products during one 3-12 month period.

   If the worker stops using tobacco products and then restarts, the insurer will not pay for smoking cessation products again on that claim.

What does a provider need to do to get tobacco use cessation products approved on a claim?

The State Fund or Self-Insured claim manager will need to pre-approve tobacco use cessation products.
First the surgeon must show that the worker is a candidate for a spinal fusion.

For State Fund claims, the surgeon must call the Utilization Review vendor, Qualis Health, to initiate the review for the spinal fusion. Qualis Health can be reached at 1-800-541-2894 or locally at (206) 366-3360 or by FAX at 1-877-665-0383 or (206) 366-3378.

The surgeon should indicate to Qualis Health that he/she wants the worker to stop smoking and that the worker needs tobacco use cessation products to do so. Qualis Health will initiate the review for the spinal fusion and ask the surgeon to call the State Fund claim manager to get authorization to use smoking cessation products. Only the claim manager can authorize purchase of the tobacco use cessation products.

To finish the review for spinal fusion, the surgeon's office will need to call Qualis Health at a later time to notify them of the date surgery is scheduled. Surgery should coincide with the worker having been off all nicotine products for at least 90 days.

Where is more information available?

Contact Grace Wang at wann235@lni.wa.gov or (360) 902-5227 for more information about technology assessments. Assessments are available online at http://www.lni.wa.gov/omd/MedCov.htm.

For additional information about fees and billing instructions, see the Medical Aid Rules and Fee Schedules. That information may be found online at http://www.lni.wa.gov/hsa/marfs/default.htm